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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,601	04/28/2006	William Suttle Peters	13634.4011	3338

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ORRICK, HERRINGTON & SUTCLIFFE, LLP
IP PROSECUTION DEPARTMENT
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EXAMINER

BEHRINGER, LUTHER G

ART UNIT	PAPER NUMBER
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3766

MAIL DATE	DELIVERY MODE
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09/04/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/595,601	Applicant(s) PETERS ET AL.	
	Examiner Luther G. Behringer	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 April 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This office action is in response to the communication received on 07/08/2009 concerning application no. 10/595601 filed on 04/28/2006.

Response to Arguments

2. Applicant's arguments with respect to claim 07/08/2009 have been considered but are moot in view of the new ground(s) of rejection.

3. Applicant argued that the device of Kapp failed to satisfy the requirements of a "heart assist device." However, the prior art device of Kapp, with the exception of a microphone, contains all of the elements of claim 39, qualifying it as a heart assist device. If a prior art structure is capable of performing the intended use as recited in the preamble, then it meets the claim. See, e.g., *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997) In addition, the example presented by Kapp of placing the invention on the carotid artery does not limit the placement of the invention to that specific artery.

Claim Rejections - 35 USC § 103

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claim(s) 39 – 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Kapp et al. (US 4,256,094, herein Kapp)** in view of **Anonymous, "Use of Heart Valve**

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Sounds as Input to Cardiac Assist Devices” (previously cited) in view of **Lekholm (US 4,763,646)** (cited in an IDS).

With regard to **claim 39**, Kapp discloses an apparatus for controlling the pulsations of a heart assist device wherein said heart assist device comprising: a pump for generating fluid pressure, **26**; an inflatable cuff, **12**, for applying said pressure to blood in a blood vessel; a fluid, *water*, for transmitting said pressure between said pump for generating fluid pressure and said inflatable cuff for applying said pressure (Fig. 1; Col. 1, ll. 65 – Col. 2, ll. 7), but fails to disclose positioning a microphone within said fluid, the microphone being adapted to detect heart sounds in said blood vessel.

It is known in the art, as demonstrated by the article by Anonymous in Research Disclosure, that heart sounds may be utilized to control pulsatile cardiac assist devices including intra-atrial blood pumps, cardiomyoplasty/cardiac assist devices, aortomyoplasty and ventricular assist devices.

6. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate a heart sound responsive controller into the heart assist device of Kapp. Kapp discloses the claimed invention except for a heart sound responsive controller instead of pressure responsive feedback system. Anonymous shows that a heart sound responsive controller is an equivalent structure known in the art. Therefore, because the two controllers were art recognized equivalents at the time of the invention was made, one of ordinary skill in the art would have found it obvious to substitute the heart sound responsive controller for the pressure responsive controller, since substitution of one known element for another would have yielded predictable results.

While Anonymous demonstrates the general concept of controlling pulsatile assist devices utilizing heart sounds, he fails to disclose positioning a microphone within said fluid, the microphone being adapted to detect heart sounds in said blood vessel.

However, Lekholm has demonstrated that placement of transducers within fluid filled lumens is known in the art. Lekholm contemplates those transducers as being pressure sensors, accelerometers or sound sensors (Col. 3, l. 47 – Col. 4, l. 16).

7. Since the marketplace reflects the reality that applying modern, more compact electronics to older electronic devices is commonplace, it would have been obvious to one of ordinary skill in the art of electrical medicinal therapy at the time of the invention to update the device of Kapp in view of Anonymous with the modern implantable electronics that are commonly available and understood in the art as shown in Lekholm in order to gain the commonly understood benefits of such adaptation, such as increased reliability, reduced size, simplified operation and reduced cost.

Regarding **claim 40**, Kapp in view of Anonymous in view of Lekholm discloses wherein said heart sounds detected by the microphone are utilized in controlling the operation of said heart assist device (Anonymous: Abstract).

With regard to **claim 42**, Kapp in view of Anonymous in view of Lekholm discloses wherein said pressure is directly applied to the exterior of said blood vessel (Kapp: Fig. 1).

Regarding **claim 43**, Kapp in view of Anonymous in view of Lekholm discloses wherein said pressure is applied to the exterior of an artery but is silent as to the location of that artery.

8. Kapp in view of Anonymous in view of Lekholm discloses the claimed invention except for specifically placing the cuff on the aorta. It would have been obvious to one having ordinary skill in the art at the time the invention was made to place the cuff on the aorta, an artery, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

With regard to **claim 44**, Kapp in view of Anonymous in view of Lekholm discloses wherein said pressure is applied to said inflatable cuff and said inflatable cuff in turn applies said pressure to the exterior of said blood vessel (Kapp: Fig. 1).

Regarding **claim 45**, Kapp in view of Anonymous in view of Lekholm discloses wherein said heart assist device initiates a change in its pulsatile state in response to electrical detection of an R-wave in a patient's heart rhythm and returns to the pulsatile state it had before the preceding R-wave in response to said microphone detecting said heart sound created by closure of the patient's aortic valve (Lekholm: Col. 1, ll. 28 – 41).

With regard to **claim 46**, Kapp in view of Anonymous in view of Lekholm discloses wherein said inflatable cuff includes a flexible membrane, *elastic liner*, and said flexible membrane applies said pressure to the blood in the blood vessel (Kapp: Fig. 1; Col. 3, ll. 7 – 19).

Regarding **claim 47**, Kapp in view of Anonymous in view of Lekholm discloses wherein said fluid is a liquid (Kapp: Col. 1, ll. 65 – Col. 2, ll. 7).

With regard to **claim 48**, Kapp in view of Anonymous in view of Lekholm discloses wherein said fluid is a gas (Kapp: Fig. 3; Col. 4, ll. 18 – 56).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Luther G. Behringer whose telephone number is (571)270-3868. The examiner can normally be reached on Mon - Thurs 9:00 - 6:30; 2nd Friday 9:00 - 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Carl H. Layno/
Supervisory Patent Examiner, Art Unit 3766

/Luther G Behringer/
Examiner, Art Unit 3766